



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	· FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/551,579	03/30/2006	Lawrence Mayer	532552000701 3865		
25225 MORRISON &	7590 07/06/2007 & FOERSTER LLP		EXAMINER		
12531 HIGH BLUFF DRIVE			KISHORE, GO	DLLAMUDI S	
SUITE 100 SAN DIEGO, CA 92130-2040			ART UNIT	PAPER NUMBER	
•			1615		
				251 11 1551 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
			MAIL DATE	DELIVERY MODE	
•			07/06/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/551,579	MAYER ET AL.			
Office Action Summary	Examiner	Art Unit			
	Gollamudi S. Kishore, Ph.D	1615			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1) Responsive to communication(s) filed on	<b>_</b> ·				
,	,—				
	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4)⊠ Claim(s) <u>1-33</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6) Claim(s) is/are rejected.					
<ul> <li>7) ☐ Claim(s) is/are objected to.</li> <li>8) ☒ Claim(s) 1-33 are subject to restriction and/or example.</li> </ul>	election requirement.				
O/ES Claim(6) 1-65 are subject to restriction arrays, steeling requirements					
Application Papers					
9) The specification is objected to by the Examiner.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
,					
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) All b) Some * c) None of:					
<ul><li>1. Certified copies of the priority documents have been received.</li><li>2. Certified copies of the priority documents have been received in Application No</li></ul>					
3. Copies of the certified copies of the priority documents have been received in Application No					
application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s)					
1) Notice of References Cited (PTO-892)	4) Interview Summary				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da 5) Notice of Informal F				
Information Disclosure Statement(s) (PTO/SB/08)     Paper No(s)/Mail Date	6) Other:	the second of			

Application/Control Number: 10/551,579 Page 2

**Art Unit: 1615** 

## **DETAILED ACTION**

## Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Claims 1-27 and 29-32 are, drawn to a liposome composition comprising delivery vehicles containing two therapeutic agents and a method of treating a disease, classified in class 424, subclass 450.
  - II. Claim 28 is, drawn to a method of preparation of the composition, classified in class 264, subclass 4.1, class 435, subclass 4 plus.

The inventions are distinct, each from the other because of the following reasons:

- III. Claim 33 is, drawn to a method to deliver a composition containing a first delivery vehicle and second delivery vehicle, classified in class 424, subclasses vary depending upon the vehicle, liposomes for examples in subclass 450.
- 2. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the mole ratios can be determined in vivo in animal models.
- 3. Inventions I and III are independent and distinct in that the composition in Group I is a single liposome composition whereas the composition in Group III requires two vehicles which can be micelles, liposomes, microspheres etc.

Application/Control Number: 10/551,579 Page 3

Art Unit: 1615

4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

- 5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.
- 6. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Application/Control Number: 10/551,579 Page 4

Art Unit: 1615

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/551,579

Art Unit: 1615

,579 Page 5

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Collamudi S Kishore, Ph.D

Primary Examiner
Art Unit 1615

**GSK**